

Vedolizumab (Entyvio®)

This sheet is about exposure to vedolizumab in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is vedolizumab?

Vedolizumab is a medication that has been used to treat inflammatory bowel diseases such as ulcerative colitis (UC) and Crohn's disease (CD). It is a monoclonal antibody that helps stop gut inflammation (swelling and irritation).

Vedolizumab is given by intravenous (IV) infusion (through a vein in the arm). The brand name for vedolizumab is Entyvio®. For more information on UC and CD, please see the MotherToBaby fact sheet on Inflammatory Bowel Disease (IBD) at <https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/>.

Sometimes when people find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

I am taking vedolizumab, but I would like to stop taking it before getting pregnant. How long does the drug stay in my body?

People eliminate medication at different rates. In healthy adults, it takes up to 150 days, on average, for most of the vedolizumab to be gone from the body.

I take vedolizumab. Can it make it harder for me to get pregnant?

It is not known if vedolizumab can make it harder to get pregnant.

Does taking vedolizumab increase the chance for miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Based on the studies reviewed, it is not known if vedolizumab increases the chance for miscarriage. Limited information suggests no increase in the chance of miscarriage when vedolizumab is used during pregnancy.

Does taking vedolizumab increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. Based on the studies reviewed, it is not known if vedolizumab increases the chance of birth defects above the background risk. Limited information does not suggest an increased chance of birth defects when vedolizumab is used during pregnancy.

Does taking vedolizumab in pregnancy increase the chance of other pregnancy-related problems?

Based on the studies reviewed, it is not known if vedolizumab can cause other pregnancy-related problems, such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth).

Does taking vedolizumab in pregnancy affect future behavior or learning for the child?

Based on the studies reviewed, it is not known if vedolizumab increases the chance for behavior or learning issues.

Breastfeeding while taking vedolizumab:

Vedolizumab has not been well-studied for use during breastfeeding. There are case reports of use of vedolizumab during breastfeeding without side effects in the nursing infants. Vedolizumab is a very large protein, so not much of the medication is expected to pass into breast milk. Vedolizumab is also poorly absorbed from the infant's gut, so it is unlikely that the infant would be exposed to much of the medication. If you suspect the baby has any symptoms (fever, frequent infections, trouble with feeding, or trouble with weight gain) contact the child's healthcare provider. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a male takes vedolizumab, could it affect fertility (ability to get partner pregnant) or increase the chance of birth defects?

Studies have not been done to see if vedolizumab could affect male fertility. No birth defects were reported in 11 pregnancies in which male partners used vedolizumab. In general, exposures that fathers or sperm donors have are unlikely to increase the risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/>.

MotherToBaby is currently conducting a study looking at vedolizumab and other medications used to treat UC and CD in pregnancy. If you are interested in taking part in one of these studies, please call 1-877-311-8972 or visit <https://mothertobaby.org/join-study/>.

Selected References:

- Bell C, et al. Systematic review and meta-analysis: Safety of vedolizumab during pregnancy in patients with inflammatory bowel disease. *J Gastroenterol Hepatol*;36(10):2640-2648. PMID: 34110640 DOI: 10.1111/jgh.15574
- Gisbert JP, et al. 2020. Safety of New Biologics (Vedolizumab and Ustekinumab) and Small Molecules (Tofacitinib) During Pregnancy: A Review. *Drugs*;80(11):1085-1100. PMID: 32562207 DOI: 10.1007/s40265-020-01346-4
- Julsgaard M, et al. 2017. Vedolizumab safety in pregnancy and newborn outcomes. *Gut*; 66(10):1866-1867.
- Julsgaard M, et al. 2018. Vedolizumab concentrations in the breast milk of nursing mothers with inflammatory bowel disease. *Gastroenterology* 154: 752-765.
- Lahat A, et al. 2018. Vedolizumab levels in breast milk of nursing mothers with inflammatory bowel disease. *J Crohns Colitis*; 12:120-3.
- Lamb CA, et al. 2019. British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. *Gut* ;68(Suppl 3):s1-s106. PMID: 31562236 PMCID: PMC6872448 DOI: 10.1136/gutjnl-2019-318484
- Laube R, et al. 2021. Use of medications during pregnancy and breastfeeding for Crohn's disease and ulcerative colitis. *Expert Opin Drug Saf* ;20(3):275-292. PMID: 33412078 DOI: 10.1080/14740338.2021.1873948
- Mahadevan U, et al. 2017. Vedolizumab exposure in pregnancy: Outcomes from clinical studies in inflammatory bowel disease. *Aliment Pharmacol Ther*; 45:941-950.
- Mahadevan U, et al. 2017. Editorial: vedolizumab in pregnancy - is gut selectivity as good for baby as it is for mum? Authors' reply. *Aliment Pharmacol Ther*. 45(9):1284.
- Moens A, et al. 2019. Outcome of pregnancies in female patients with inflammatory bowel diseases treated with vedolizumab. *J Crohns Colitis* 13(1): 12-13.

- Moens A, et al. 2020. Pregnancy outcomes in inflammatory bowel disease patients treated with vedolizumab, anti-TNF or conventional therapy: results of the European CONCEIVE study. *Aliment Pharmacol Ther* 51(1): 129-138.
- Rosario M, et al. 2017. A Review of the Clinical Pharmacokinetics, Pharmacodynamics, and Immunogenicity of Vedolizumab. *Clin Pharmacokinet*. 2017; 56(11): 1287–1301. PMCID: PMC5648740 PMID: 28523450
- Sheridan J, et al. 2017. Letter: Vedolizumab in Pregnancy. *J Crohns Colitis*; 11(8):1025-1026.
- Shitrit AB-G A, et al. 2019. Exposure to vedolizumab in IBD pregnant women appears of low risk for mother and neonate: A first perspective comparison study. *Am J Gastroenterol* 114(7): 1172-1175.
- Takeda Pharmaceuticals America, Inc. 2018. Entyvio product label. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6e94621c-1a95-4af9-98d1-52b9e6f1949c>

